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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,822	07/22/2003	Mitali Ghoshal	RDID0086DUS	9424

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EXAMINER

HAQ, SHAFIQUK

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,822

Applicant(s)

GHOSHAL ET AL.

Examiner

Shafiqul Haq

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Election/Restrictions

1. Applicants' response filed July 13, 2006 to election requirement in Office Action mailed June 13, 2006 is acknowledged and entered.

Applicants' election with traverse of Group II, Claims 3-5, 7 and 11 is acknowledged. Applicants' traversal is on the grounds that the elected Group II should include claims 10 and amended claim 11 (correction of dependency) and claim 7 should properly be included in group I. Applicants further argued that Group I should properly include claims 1, 2 and 6-9 because the feature of antibody produced in response to the compound having a carrier on the aminoglycoside compound in claims 1 and 2 is required by the method of claim 6 and 7 and by the kit of claims 8 and 9. Applicants' argument with regard to elected Group II is persuasive and therefore, Group II should include claims 3-5, 10 and 11. However, Applicants' argument with regard to group I is not persuasive because claim 1 and 2 are antibody claim and claims 6-9 method of using the antibody and the antibody in a package combination with analog-label complex. Therefore, claims 1, 2 and 6-9 should be properly separated in two groups i.e. Group I (claims 1-2) and Group III (claims 6-9). Group I and Group III are related as product and process of use but the inventions are distinct because the product (i.e. antibody) of Group I can be practiced with another materially different process, such as isolation or purification of aminoglycosides. The reasons as set forth in paragraph 3 of last office action are

still valid for the distinctiveness of Group II and III. Therefore, the new grouping necessitated by applicants' argument and amendments are as below:

- I. Claims 1 and 2, drawn to an antibody, classified in class 530, subclass 387.1.
- II. Claims 3-5, 10 and 11 drawn to a method for determining aminoglycoside, classified in class 435, subclass 7.1.
- III. Claims 6-9, drawn to a method of determining aminoglycoside, classified in class 435, subclass 7.95.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to

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rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Accordingly, Claims 1-2 and 6-9 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Claims 3-5, 10 and 11 are examined on merits.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47 of U.S. Patent No. 6,653,456 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 47 of referenced U.S. Patent are drawn to a test kit for determining aminoglycoside analyte in a sample comprising in packaged combination, an antibody specific for the analyte and a reagent comprising compound (referred to claim 41 compound), which is the same as the reagent of claim 10 of present application. The label (claim 11) of present application is the same as the label of formula (X) of claim 41 of referenced patent. Therefore, the "label" of present application encompasses label of the patent.

The only difference is that in present application, the phrase "antibody specific for the aminoglycoside" is recited in claim 10, whereas in the referenced patent, "antibody specific for the analyte" is recited. One of ordinary skill in the art would readily understand that for determining an aminoglycoside analyte, the "antibody specific for the analyte" should be specific for aminoglycoside in the sample as recited in present application. Therefore, the kit in packaged combination of the US patent would be obvious in view of the above discussion.

Allowable Subject Matter

5. Claims 3-5 are free of art and are allowable. Claims 10-11 would be allowable if a terminal disclaimer is timely filed in compliance with 37 CFR 1.321(c) or 1.321(d) to overcome obviousness double patenting rejection as set forth in this office action.

Conclusions

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Natrajan et al. (2003/0045716 A1), disclose tobramycin tracer for immunoassay comprising tobramycin conjugate wherein a label is conjugated with tobramycin at 5' position of the tobramycin (see fig. 6 and paragraph [0029]), but the position of the label is different from the conjugate (tracer) (at position 1 and 4") present application.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EXAMINER
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